REMARKS/ARGUMENTS

Claims 1, 7 and 10-23 are pending, claims 14-23 having been withdrawn from consideration. By this Amendment, claims 1 and 13 are amended. Support for the amendments to claims 1 and 13 can be found, for example, in the present specification at page 13, lines 10 to 15, and in previously presented claims 1 and 13. No new matter is added. In view of the foregoing amendments and following remarks, reconsideration and allowance are respectfully requested.

Personal Interview

Applicants appreciate the courtesies extended to Applicants' representative by Examiners Palenik and Wax during the July 29, 2011 Personal Interview. Applicants' separate record of the substance of the interview is incorporated in the following remarks.

Withdrawn Claims

For the reasons set forth below, Applicants submit that all pending claims presently subject to examination are in condition for allowance. Because the withdrawn claims depend from, and thus recite all features of, allowable claim 1, rejoinder and allowance of the withdrawn claims are respectfully requested.

Objection to the Claims

The Office Action objects to claim 1. By this Amendment, claim 1 is amended, as proposed by the Examiners during the Personal Interview, to obviate the objection. Accordingly, reconsideration and withdrawal of the objection are respectfully requested.

Rejection Under 35 U.S.C. §112, Second Paragraph

The Office Action rejects claims 1, 7, and 10-13 as indefinite under 35 U.S.C. §112, second paragraph. By this Amendment, claim 1 is amended, as proposed by the Examiners during the Personal Interview, to obviate the rejection. Claims 7 and 10-13 are rejected solely for their dependency from claim 1. Accordingly, reconsideration and withdrawal of the objection are respectfully requested.

Rejection Under 35 U.S.C. §103

The Office Action rejects claims 1, 7 and 10-13 under 35 U.S.C. §103(a) over U.S. Patent Application Publication No. US 2004/0058956 to Akiyama et al. ("Akiyama") in view of U.S. Patent No. 5,538,728 to Yanaki et al. ("Yanaki") and EP 1 323 786 to Iwahashi et al. ("Iwahashi"). By this Amendment, claims 2-4 are cancelled, rendering the rejection moot as to those claims. As to the remaining claims, Applicants respectfully traverse the rejection.

Claim 1 recites "[a] composition, comprising: a very low water-soluble drug; and a porous silicon material; wherein: the composition is produced by treating a mixture comprising the very low water-soluble drug and the porous silicon material with a supercritical or subcritical carbon dioxide fluid; the very low water-soluble drug has a solubility in water at 25 °C of less than 10 μg/mL prior to treatment; the porous silicon material comprises at least one member selected from the group consisting of light anhydrous silicic acid, hydrated silicon dioxide, silicon dioxide, and calcium silicate; the porous silicon material is not a porous silica material having all of the following: an average pore diameter of 1 to 20 nm; 60% or more of a volume of all of the pores of the porous silica material have a diameter falling within a range of ± 40% of the average pore diameter; and an X-ray diffraction pattern including one or more peaks at a diffraction angle (2θ) corresponding to d of 1 nm or more; the porous silicon material has an average pore diameter of 1 to 500 nm; the

porous silicon material has a specific surface area of 100 to 1,800 m^2/g; and the composition is suitable for oral administration" (emphasis added). Akiyama, Yanaki, and Iwahashi do not disclose or suggest such a composition.

It is undisputed that none of the cited references discloses or suggests a composition including a mixture of a very low water-soluble drug and a porous silicon material, which is obtained by treating the mixture with a supercritical or subcritical carbon dioxide fluid. The Office Action asserts that this feature (treating the mixture with a supercritical or subcritical carbon dioxide fluid) should be given no weight as a product-by-process feature. *See* Office Action, pages 8 to 9. While "the patentability of a product does not depend on its method of production," it is also true that the structure implied by process steps should be considered when assessing patentability. *See* MPEP §2113. In this case, by treating the mixture with a supercritical or subcritical carbon dioxide fluid, a composition is obtained that has different properties from composition that is not obtained by being subjected to such a treatment.

As agreed during the Personal Interview, the experimental results in the present specification confirm the foregoing assertion. *See* present specification, TABLE 1 (reproduced below). For example, Example 1 and Comparative Example 1 include the same very low water-soluble drug and the same porous silicon materials in the same amounts. The two compositions differ in that, the composition of Example 1 was obtained by mixing in the presence of dry ice (as required in claim 1), while the composition of Comparative Example 1 was prepared without dry ice (as in, e.g., Akiyama). By virtue of the manner in which the respective compositions were obtained, the composition of Example 1 is substantially more soluble (at each of 5, 30, 60, and 120 minute stirring times). Thus, compositions according to claim 1 are substantially more soluble than otherwise identical compositions that are not obtained by treating a mixture of a very low water-soluble drug and a porous silicon material with a supercritical or subcritical carbon dioxide fluid.

TABLE 1

		Example								Comparative Example			
		1	2	3	4	5	6	7	8	1	2	3	4
Compound A (mg)		30	30	30	30	30	30	800	—	30	30	—	—
Prednisolone valerate acetate (mg)		—	—	—	—	—	—	—	30	—	—	30	30
Hydrated silicon dioxide, Sylysia 740 (mg)		300	—	—	—	—	—	—	—	300	—	—	—
Light anhydrous silicic acid, Sylysia 350 (mg)		—	300	—	—	—	—	4000	300	—	—	300	—
Silicon dioxide, Sylysia 250 (mg)		—	—	300	—	—	—	—	—	—	—	—	—
Silicon dioxide, Sunsphere H-51 (mg)		—	—	—	300	—	—	—	—	—	—	—	—
Calcium silicate, Florite RE (mg)		—	—	—	—	300	—	—	—	—	—	—	—
Light anhydrous silicic acid, Aerosil 300 (mg)		—	—	—	—	—	300	—	—	—	—	—	—
Dry ice (g)		120	120	120	120	120	120	—	120	—	120	—	120
Liquefied carbon dioxide (g)		—	—	—	—	—	—	460	—	—	—	—	—
Average pore diameter (nm)		2.5	21	24	5	150	—	21	21	2.5	—	21	—
Percent dissolution (%)	Stirring time (minutes) 5	15.5	85.6	91.6	36.2	55.8	87.4	90.6	57.1	3.1	0.0	12.0	0.4
	30	42.6	96.7	96.7	77.6	61.4	92.3	97.0	83.7	5.3	1.7	37.4	0.8
	60	48.9	96.8	96.9	82.4	64.7	93.6	97.0	88.0	7.5	1.1	46.0	1.3
	120	57.4	97.6	98.6	80.5	63.1	91.9	96.6	89.2	11.8	2.2	53.8	3.0

Accordingly, even if the cited references were deemed to suggest a mixture of a very low water-soluble drug and a porous silicon material as required in claim 1, because the cited references indisputably fail to disclose or suggest treating the mixture with a supercritical or subcritical carbon dioxide fluid, the cited references fail to disclose or suggest a composition having the properties of the composition of claim 1.

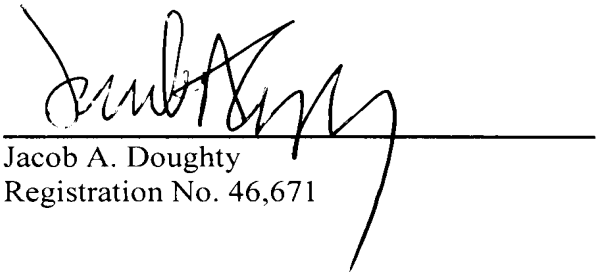
As explained, claim 1 would not have been rendered obvious by Akiyama, Yanaki, and Iwahashi. Claims 7 and 10-13 depend from claim 1 and, thus, also would not have been rendered obvious by Akiyama, Yanaki, and Iwahashi. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

For the foregoing reasons, Applicants submit that claims 1, 7 and 10-23 are in condition for allowance. Prompt reconsideration and allowance are respectfully requested.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



Jacob A. Doughty
Registration No. 46,671

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 08/07)